

Wednesday, Sept 10, 2009

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov
SPL technical questions? Send to spl@fda.hhs.gov

Meeting Minutes:

**1. Content of labeling for combination products including "convenience kits."
(Confirmation regarding whether or not convenience-kit-w/medical-device-as-lead-product SPL documents should include content of labeling for drug products)**

Convenience kit could include a medical device, or several different drugs approved by CDER.

Q: Should companies producing convenience kits include the content of labeling for products produced by someone else?

CDER wants convenience kits registered, so both CDRH and CDER have the registration.

A: Content of labeling is required for all drug products in the convenience kit. Doesn't matter what order the product content-of-labelings appear in.

Convenience kits don't get submitted to CDER (although the Division reviewed the individual product(s)).

If the convenience kit contains

- only Rx approved products, the file **can be transmitted** to DailyMed.*
- both Rx approved products and approved OTC products with application numbers, the file **can be transmitted** to DailyMed.*
- one or more unapproved products, or OTC products without application numbers, it **will not be transmitted** to DailyMed.*

Q: Same issue for repackers – should the manufacturers SPL be included in the drug listing file?

A: Yes, they should be included.

Note: Combination drug training has been postponed pending discussion within the FDA on how specifically to handle convenience kits. Look for rescheduling soon.

Suggestion: Would be great to have a consistent way of presenting the separation between the content of labelings. Perhaps the FDA could consider this as part of future guidance(s)

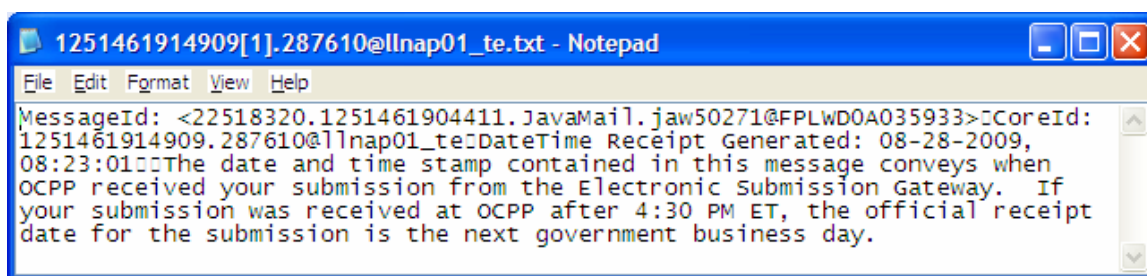
*Some options: ***** or SPL Unclassified or -----*

2. Requests for submission status requests for SPL R4 documents

Recently approved SPL not appearing on DailyMed – possible reasons: market start date sometime in the future. To fix, change the market status date to a date earlier than today, and resubmit.

To request the status of a submitted drug listing SPL, include the CoreId in your e-mail. The CoreId is included in the Gateway file. If it's for an approved Rx or for VetMed, they will go through to DailyMed if there are no validation errors.

To find a CoreId, look in the receipt or first acknowledgement, which usually looks something like this:



For this example, the parts of the e-mail have been separated. The CoreId is in red text (for emphasis)

```
MessageId: 22518320.1251461904411.JavaMail.hxw53272@FPLWD0A035933
CoreId: 1251461914909.287610@llnap01_te
DateTime Receipt Generated: 08-28-2009, 08:23:01
```

The date and time stamp contained in this message conveys when OCPP received your submission from the Electronic Submission Gateway. If your submission was received at OCPP after 4:30 PM ET, the official receipt date for the submission is the next government business day.

Q: Troubleshooting your SPL errors – what do you do when you can't see the XML file [correctly]?

A: PDFs are often screen captures. If you receive a PDF from the person or group that submitted your SPL, it may not capture the full text of the message. Instead, they should download the file as an xml file.

A: If you can't view the XML In your browser, check the Security settings:

*IE: Tools > Security Settings > Custom Level > Miscellaneous (across domains)
Can try via Trusted Sites [contact the IT dept to add the trusted site, update browser site]*

A: Within Webtrader :

A: Synchrony: second acknowledgement includes the XML file. Three things will be available: One is the signed and encrypted message, one is the actual Sent file (download and save as xml).

*When you try to view the document – download the document from your computer.
View it as XML*

3. Updated SPL R4 Validation Procedures

Link to changes: <http://spl-work-group.wikispaces.com/Validation+Rules+Modifications>

Possible future additions to validation rules:

Suggested (so fix these before they cause a validation error):

- *If the SPL has a doc type of bulk ingredient, there can't be more than 1 bulk ingredient in the file.*
- *Route of administration for bulk ingredient = Not applicable*
- *A generic name should not include 'USP'*

Also, spaces at the end of the fields (either with the space bar, or copy & paste from word processing to XML field) can lead to inconsistencies in searching, and a possible validation error. The eList application counts spaces just like any other character.

Example: ASPIRIN_ and ASPIRIN both display as ASPIRIN on the screen; however, the application will treat these as different terms.

Make sure spaces are removed.

4. Follow up discussion on de-listing

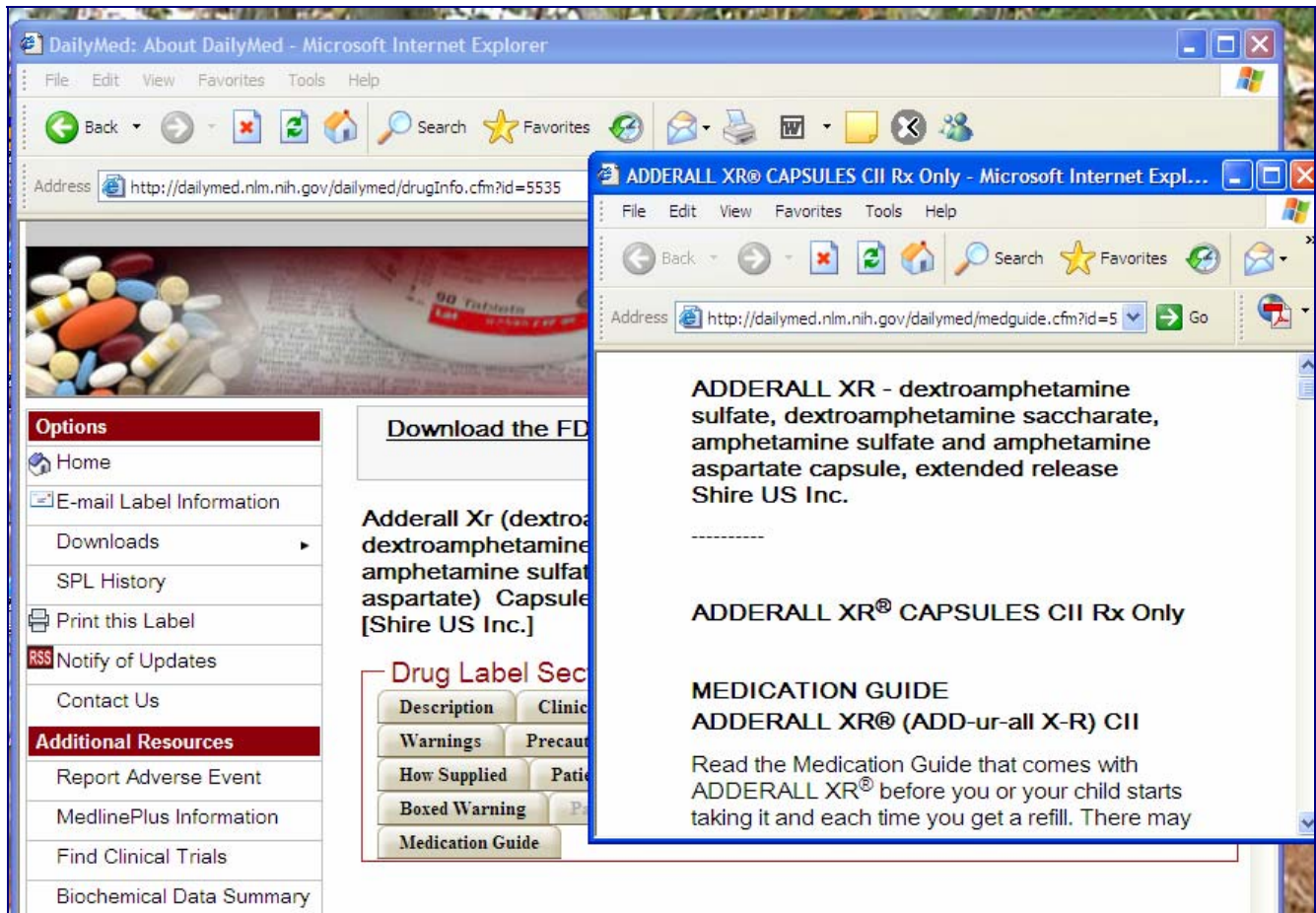
Several suggestions being discussed further w/in ER/DL subgroup.

If you submit a SPL file for a product that's not in the eList file (but the NDC code directory contains the NDCs for that SPL) – how do the NDC codes get removed from the old directory? eList system. ELIPS has been decommissioned.

For a product that is not on DailyMed, available only in paper. Would it be appropriate for a company to create an SPL that contains content-of-labeling that is simply a statement of the delisting (e.g., "this file is being submitted specifically for the purposes of delisting")

5. Change in display of med guides on DailyMed

SPL with Medguide sections on DailyMed can now display this in a separate pop-up window. Click on the Medguide tab within the DailyMed record. The full label will remain on the screen. A second window will open showing only the patient-oriented information.



Currently there are 4981 SPL on [DailyMed](http://dailymed.nlm.nih.gov)

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